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REMARKS

Status of the Claims

Claims 5-9, 13-17, 19, 20, 26-43, and 45-49 are pending in the present application. No new matter has been added by amendment. Reexamination and reconsideration of the claims are respectfully requested.

Pursuant to 37 C.F.R. § 1.116 and the *Manual of Patent Examining Procedure* (*MPEP*), any affidavits and other evidence that will place the application in condition for allowance may be entered after final rejection (*MPEP* § 714.12). Applicants submit that the following arguments overcome the Examiner's rejection of pending claims 5-9, 13-17, 19, 20, 26-43, and 45-49, and that these claims are in condition for allowance. Accordingly, the Examiner is respectfully requested to enter this response after final into the record to further prosecution or to place the application in better condition for appeal.

The Examiner's comments in the Office Action are addressed below in the order set forth therein.

The Rejection of the Claims Under 35 U.S.C. § 103

Claims 5-9, 13-17, 19, 20, 26-43, and 45-49 were rejected under 35 U.S.C. § 103 as allegedly being obvious over Dorin *et al.* (U.S. Patent No. 5,814,485) in view of Hershenson *et al.* (U.S. Patent No. 5,004,605) and further in view of *The Merck Index* (1989). Applicants thank the Examiner for noting in the Office Action dated November 27, 2006 that Applicants' reply dated September 13, 2006 has overcome this rejection.

The Rejection of the Claims Under 35 U.S.C. § 112, First Paragraph, Written Description, Should Be Withdrawn

The Examiner has rejected claims 5-9, 13-17, 19, 20, 26-43, and 45-49 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement of Section 112. Specifically, the Examiner asserts that:

> The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the

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> relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The specification provides no written description for 'composition being free of glycerol and polyethylene glycol polymers.' Applicant on page 15, lines 22-28 of the specification does not teach that the addition of stabilizers such as glycerol is optional. Therefore, the recitation of 'composition being free of glycerol and polyethylene glycol polymers' is considered 'new matter'."

Office Action, page 3, lines 2-10; emphasis in original. This rejection is respectfully traversed.

The Federal Circuit has made it clear that sufficient written description requires simply the knowledge and level of skill in the art to permit one of skill to immediately envision the product claimed from the disclosure. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) ("One skilled in the art must immediately discern the limitations at issue in the claims."). In the instant case, the Examiner asserts that the specification provides no written description support for compositions being free of glycerol and polyethylene glycol polymers. Applicants respectfully disagree with this assertion and submit that a careful reading of the section of the specification cited by the Examiner (*i.e.*, page 15, lines 22-28), as well as a careful reading of the application as a whole, allows one skilled in the art to "immediately discern the limitations at issue in the claims" (*Purdue Pharma*, 230 F.3d at 1323).

Specifically, the specification discloses that:

> Following the diafiltration or dialysis step with a pharmaceutically acceptable buffer of choice to remove residual guanidine HCl, the resulting pharmaceutical compositions **may** be stabilized against denaturation and loss of biological activity by the inclusion of a stabilizer in the pharmaceutical compositions ...

Page 15, lines 22-26 (emphasis added). As the specification clearly teaches that the disclosed pharmaceutical compositions **may** be stabilized by inclusion of a stabilizer, Applicants submit that the specification does provide written description support for the limitation "composition being free of glycerol and polyethylene glycol polymers," such that one skilled in the art could immediately discern the limitation at issue. Indeed, the Federal Circuit has stated that "the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue." *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1376, 62 USPQ2d 1917, 1922 (Fed. Cir. 2002).

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Additionally, as noted above, Applicants submit that a careful reading of the application as a whole further provides written description support for the limitation "composition being free of glycerol and polyethylene glycol polymers," such that one skilled in the art could immediately discern the limitation at issue. For example, a careful review of the Experimental section of the application shows that the disclosed pharmaceutical compositions comprising interferon-beta (IFN-β) do **not** include a stabilizer (such as glycerol or polyethylene glycol polymers); that is, the compositions are "free of glycerol and polyethylene glycol polymers." As the Federal Circuit has made clear, "compliance with the written description requirement requires that the original application considered as a whole describe the invention claimed in the patent resulting from the application." *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1914 (Fed. Cir. 2000). See also, *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989) (The specification as filed did not include the negative limitation "not permanently fixed" as recited in the amended claims. However, the court held that this omission was "not important," as the application's examples unequivocally taught the absence of permanently fixed microcapsules (*e.g.*, disclosing that it was important that the microcapsules not be disturbed so as to change their positions until an image was formed, showing that the microcapsules were not permanently fixed.)).

In view of the above remarks, Applicants submit that the application as a whole provides necessary and sufficient written description support for the limitation "composition being free of glycerol and polyethylene glycol polymers." Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection of claims 5-9, 13-17, 19, 20, 26-43, and 45-49 under 35 U.S.C. § 112, first paragraph, written description.

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CONCLUSION

In view of the foregoing remarks, Applicants respectfully submit that the rejection of the pending claims under 35 U.S.C. § 112 is overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned attorney.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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CERTIFICATION OF FACSIMILE TRANSMISSION
I hereby certify that this paper is being facsimile transmitted to the US Patent and Trademark Office, Mail Stop AF, at Fax No. (571) 273-8300 on the date shown below.

David E. Cash 2/27/07

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